REMARKS

Applicants have amended the claims in order to more particularly define the invention taking into consideration the outstanding Official Action and the interview with the Examiner. The Examiner is thanked for the courtesy of the interview extended Applicants' representatives who traveled from Sweden to attend the interview, and the undersigned attorney. During the interview the Examiner expressed a concern that in applying the broadest possible interpretation to the claim language, "foodstuff prepared from cereals having enzymatic activity", the prior art was included. That is, it is the Examiner's position that this limitation did not distinguish over the prior art malted cereals which at one time had enzymatic activity even though this activity was substantially destroyed during subsequent processing in the prior art. That is, sufficient enzymatic activity is required for the presently claimed invention. In order to overcome the Examiner's concern, claim 26 has been amended by stating that the foodstuffs comprise cereals having enzymatic activity to clearly distinguish over the prior art.

This amendment to the claims was discussed at the interview since it was emphasized by Applicants' representative that the prior art relied upon by the Examiner in the rejections did not contain foodstuffs which had the necessary enzymatic activity as required by the claims of the present application. However, the Examiner stated that he would not allow entry of such an amendment at this stage in the prosecution as it raised a new issue. In order to have the Examiner consider claims with this amendment, a Request for Continued Examination (RCE) is filed herewith along with an amendment to clarify the claims and further distinguish over the prior art of record and place the application in condition for allowance. This continues the prosecution of the amended claims and avoids the necessity of proceeding with the appeal.

In addition to the amendment to claim 26, claims 26 and 27 have been combined and rewritten as new claim 42 also containing the same limitation as added to claim 26 in the present amendment. In view of this, claims 27-32 and clams 35-40 have been canceled from the application without prejudice or disclaimer and replaced with corresponding claims 43-55. Applicants most respectfully submit that all of the claims

now present in the application are in full compliance with 35 USC 112 and are clearly patentable over the references of record.

The rejection of claims 26-28, 30 and 31 as being anticipated under 35 USC 102(b) by Johnston (US 5,665,225) has been carefully considered but is most respectfully traversed in view of the amendments to the claims which now clearly distinguish over the prior art as discussed above and distinguish over the facts in the Ex parte Novitski decision cited in the final rejection.

Applicants again wish to direct the Examiner's attention to MPEP § 2131 which states that to anticipate a claim, the reference must teach every element of the claim.

> "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed Cir. 1989). The elements must be arranged as required by the claim, but this is not an *ipsissimis verbis* test, i.e., identity of terminology is not required. *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed.Cir. 1990).
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> *Akzo N.V. v. International Trade Comm'n*, 808 F.2d 1471, 1 USPQ2d 1241 (Fed. Cir. 1986) (Claims to a process for making aramid fibers using a 98% solution of sulfuric acid were not anticipated by a reference which disclosed using sulfuric acid solution but which did not disclose using a 98% concentrated sulfuric acid solution.).

Applicants most respectfully submit that one of ordinary skill in the art would fully appreciate that Johnston teaches that a mixture of soy flour and particularly malted barley, stirred into water, prevents the occurrence of diarrhea in young animals. However, a very important aspect, compared to the presently claimed invention, is not mentioned by the Examiner, viz. that Johnston's method is used for preventing diarrhea caused by allergic reactions to the soy flour.

As is well known, diarrheas result from a variety of causes of which infections are an important causal complex. Elective surgery is another one. Diarrhea is a complicated

body response to different agents having different mechanisms of action. It is not at all obvious to the skilled man that a remedy for allergic diarrhea is effective for diarrhea resulting from another cause.

Applicants also appreciate that it is well known to use malt in various foodstuffs. However, there are great technical problems in preparing foodstuff with malt (except for beer) in order for them to be palatable or suitable for industrial methods of preparation. Applicants most respectfully submit that a critical condition for preventing and curing diarrhea conditions, caused by all sorts of agents, not only diarrhea caused by an allergic reaction, is to prepare the food, in accordance with the present invention, so that, upon consumption of the food, the blood will contain at least 0.5 units of antisecretory proteins per ml. This is a claim limitation which cannot be ignored and is clearly not anticipated in the reference as would be appreciated by one of ordinary skill in the art. This is not obvious from the knowledge of diarrheas. The mechanisms of fluid secretion are more complicated. Consequently, the Applicants are of the opinion that the claims on file are not anticipated by Johnston, for the reasons set forth above.

Johnston's specification and claims describe that soybean meal and (wheat) flour are mixed in a water suspension; that the mixture is gelatinised and that malt is added to this mixture. The allergenic compounds of the soybean meal are hydrolyzed, as the content of starch is hydrolyzed, according to known reactions, to glucose and dextrins. The effect of the malted cereal's enzymes on the flour mixture in a dilute water suspension forms an important part of Johnston's invention.

According to the present invention no such pre-treatment of the food is required to achieve the intended induction of antisecretory proteins. The amount of malted cereals required according to Johnston's invention, is much smaller than the amount required by the present invention. The patent description tells that preferably 1-15%, or more preferred 1-10% by dry weight grain malt (col. 3, line 5-7) is required to improve weight gain in feeding calves and lambs. Actually, Examples 1-10 report use of only 1% of malted barely. With such small amount of concentration of malt the intended effect of the present invention will not be achieved.

Products made according to Johnston's invention aim at replacing traditional milk protein-based milk-replacers for weaning calves and lambs, thus the invention aims at solving feeding problems arising when milk proteins are replaced by soybean meal flour. It seems obvious that such suspensions and solutions are not intended for human consumption, nor do they fit an industrial food manufacturing and distribution system.

Consequently, the prior art does not disclose that the effects indicated in the present invention was anticipated by Johnston's patent. In reality, the sugar and free amino acid content in malted cereals is low and is controlled by process conditions. The fact that enzymes present in malted cereals can be utilized to saccarify starch is well known, but it is novel that the malted cereals in conjunction with endogenous enzymes can digest food at such a rate and to such an extent that the desired induction of antisecretory proteins is effectively accomplished in accordance with the presently claimed invention. This is both non-obvious and novel. Accordingly, it is most respectfully requested that this rejection be withdrawn.

Applicants have carefully considered the rejection of claims 26-41 as being unpatentable under 35 USC 103(a) over Johnston, in view of Lange et al. and in further view of Robbins et al. and Aspinall et al. This rejection has been carefully considered but is most respectfully traversed.

Applicants again wish to direct the Examiner's attention to the basic requirements of a prima facie case of obviousness as set forth in the MPEP. Section 2143 states that to establish a prima facie case of obviousness, three basic criteria first must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine the reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Section 2143.03 states that all claim limitations must be taught or suggested by the prior art. In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art." In re Wilson, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. In re Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).

It is the Applicant's firm opinion that Johnston, in combination with Lange et al., Bobbins et al. and Aspinall et al., does not in any way meet the standard which is necessary to establish a prima facie case of obviousness of the presently claimed invention. Thus, as stated above, Johnston teaches a method for preventing diarrhea of young animals, caused by an allergic response to soy flour, and can thus, already for that reason, not be combined with any of the secondary references to render obvious the presently claimed invention.

On the contrary, the Lange et al patent, U.S. 5,296,243, being the inventors' own publication is acknowledged as prior art in the paragraph bridging pages 1 and 2 of the present application. The comments in therein should be noted. This prior art relates to a process for correcting and optimizing the composition of a feed for regulating the exchange of fluid and electrolytes in the gut of animals by adding certain sugars and amino acids to the feed. The objective is achieved by the fact that the addition to the feed of certain sugars and amino acids induces formation of antisecretory proteins named "feed-induced lectines" (FIL) in this patent. There is no motivation to one of ordinary skill in the art to combine this teaching with that of Johnston et al and arrive at the presently claimed invention.

The object of the present invention is to provide a foodstuff alleviating or remedying the problems and phenomena associated with undesired secretion of body fluids, and this is accomplished, according to the presently claimed invention, by regulating the net flux of fluid and electrolytes in the intestine by the addition of enzymes or compounds providing enzymatic activity. There is no suggestion of this in either Johnston et al or Lange et al, let alone in their combined teaching.

The regulation of the flux of fluid and electrolytes is achieved, according to the present invention, by using products for the preparation of foodstuff having such an enzymatic activity that the foodstuff, when consumed, induces antisecretory proteins (ASP). According to the claimed invention it has been shown that the ASP level required in order to obtain the intended effect is at least 0.5 units of ASP per ml of blood. Any product having enzymatic activity to induce the desired formation of ASP can be used. One of ordinary skill in the art to which the invention pertains, can easily, by routine tests, measure the response to the ASP induction of the foodstuff according to the method stated in U.S. 5,296,243. Briefly, the method involves measuring a standardized secretion response in the small intestine of a rat (cf. also Example 1 of the present application). It is obvious that foodstuffs prepared according to the invention can be varied in a great number of ways and be given by different embodiments. Owing to this, diet monotony can be avoided. The need of stimulation of different individuals to reach an effective ASP concentration can be met by measuring the response of food intake, as stated above. Through the invention, one can also compensate for varying activity of enzyme preparations as well as for differences in enzymatic activity between e.g. malted cereals.

It is to be noted that Lange et al does not disclose or even indicate the control of the amount of formed antisecretory proteins by the use of products having enzymatic activity in the preparation of foodstuff. (As is also evident from the International Preliminary Examination Report, the Examiner of the PCT authority considered all claims new and inventive over the prior art with respect to the corresponding PCT application.)

The use of foodstuff prepared from cereals having enzymatic activity does not require any special permit or acceptance from food inspection authorities. This is one advantage of the invention. Further, the desired effect, induction of antisecretory proteins, is safely and reproducibly achieved. The method for measuring this effect is described in the specification and suitable limits to be achieved are given. The invention enables the user of the invention to produce tasty and varying foods which provide the objective of the invention.

The known use described in Lange et al. (U.S. 5,296,243) of certain sugars and amino acids for achieving indication of antisecretory factor (protein) is in some instances impracticable. Some good inducing amino acids are not allowed as food supplement. The use of sugars and amino acids in prepared (baked, fried etc.) foods can reduce the activity of the prepared food by the formation of so-called Maillard compounds during cooking. The use of sugars can in some instances render the food an excessive unpleasant sweet taste. The invention solves this problem.

Aspinall et al. only show that the amylopectin contained in starch is more affected by the malting of barley than the amylose component that is relatively little degraded. Robbins et al. have determined the amino acid composition of the proteins of the malts of cereal species and has not determined the composition pattern of free amino acids of the malts. The reason why the amino acid composition is changed during malting is that some amino acids of the proteins are metabolized and, owing to that, the total composition of amino acids of the malted cereal proteins is changed. From this reference, the one of ordinary skill in the art cannot conclude how the composition of free amino acids of the malt is changed during malting and the combined teachings do not render obvious the presently claimed invention.

Consequently, it would not have been *prima facie* obvious to a person of ordinary skill in the art, at the time the claimed invention was made, to employ the method of Johnston for preventing diarrhea of young animals, caused by an allergic response to soar flour, in order to regulate the flux of fluid and electrolytes in the intestine of an animal since Aspinall et al. and Robbins et al. do not at all teach the composition of free amino acids of the malt upon malting of the cereals. In re Fritch, 23 USPQ 1780, 1784(Fed Cir. 1992) ("It is impermissible to engage in hindsight reconstruction of the claimed invention, using the applicant's structure as a template and selecting elements from references to fill the gaps.). Thus, the Applicants strongly assert that Johnston cannot be combined with Lange et al., Robbins et al. and Aspinall et al. in order to reject claims 21-41 under 35 U.S.C. 103(a). Accordingly, it is most respectfully requested that this rejection be withdrawn.

The same standard as discussed above applies to the rejection of claims 26-41 be rejected under 35 U.S.C. 103(a) as being unpatentable over Belles et al. and Camburn in view of Witt et al. since this combination of documents is, as firmly asserted by the Applicants, improper. Again, there must be some motivation in the prior art to modify the references to arrive at the claimed invention. This motivation may not be found in Applicants' specification and "obvious to try" is not the standard of obviousness under 35 USC 103.

Bolles et al. teach the preparation o£ a flaked cereal product having a fiber content, and this is the very purpose of Belles et al. A starch-degrading enzyme is used to degrade the starch of a bran product in order to prepare an edible anal palatable flake product. The process of Belles et al, is aimed at gelatinizing the starch fraction.

Camburn teaches solubilization of dietary fibers (an alpha-glucan containing foodstuff) comprising processing a carbohydrate-containing material under severe conditions of mechanical disruption and shear at high screw speed in an extruder. Glucans are known to reduce the cholesterol level in blood but not to normalize abnormal fluid secretion in the intestines. Therefore, Camburn does not add any knowledge of how to prepare a foodstuff for induction. of antisecretory proteins in order to achieve such a normalization.

Witt et al. teach the use of the starch-degrading enzymes of the malt to reduce the viscosity of starch pastes by liquefaction. The skilled man cannot, from this reference, draw any conclusions leading to the claimed invention.

Consequently, the combination of Belles et al., Camburn and Witt et al. to support the rejection of claims 26-41 is improper since Applicants cannot understand how the claimed invention, disclosing a method for regulating the flux of fluid and electrolytes in the intestine of an animal by feeding the animal a sufficient quantity of a foodstuff, prepared from cereals having enzymatic activity, so that 1 ml of blood of said animal will contain at least 0.5 units of antisecretory proteins, can be obvious to the skilled man reading Bolles et al., teaching the preparation of a flaked product by using starch degrading enzymes for starch gelatinization, in combination, with Camburn, teaching a mechanical process for solubilizing an alpha-glucan containing foodstuff,

and Witt et al., using the starch-degrading enzymes of the malt for liquefaction of starch. Said three references all teaches liquefaction or gelatinization of starch in order to obtain edible and palatable cereal products (flakes, dietary fibers) and do not even indicate the use of cereals having enzymatic activity to provide effective amounts of sugars and amino acids to control or govern the formation of antisecretory proteins in the foodstuff so prepared. Accordingly, it is most respectfully requested that this rejection be withdrawn.

In view of the above comments and further amendments to the claims, favorable reconsideration and allowance of all of the claims now present in the application are most respectfully requested.

Respectfully submitted,

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Marked-Up Version Showing Changes Made

IN THE CLAIMS:

Please replace claim 26 with the following amended claim 26.

26(Amended). A method for regulating the flux of fluid and electrolytes in the intestine of an animal so that 1 ml of blood of said animal will contain at least 0.5 units of antisecretory proteins which comprises feeding the animal a sufficient quantity of a foodstuff [prepared form] comprising cereals having enzymatic activity.